IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators* v. *Baxter Healthcare Corporation*	Master File No. 1:01-CV-12257-PBS
Case No. 08-CV-11200-PBS	Sub-Category Case Nos. 1:08-CV-11200-PBS & 1:10-CV-11186-PBS
United States of America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corporation and Baxter International, Inc.	Judge Patti B. Saris
Case No. 10-CV-11186-PBS	

SUN/HAMILTON'S PRE-HEARING MEMORANDUM
IN SUPPORT OF THEIR FIRST-TO-FILE POSITION

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INTRODUCTION

Under the False Claims Act, only the first complaint to reveal the essential facts of the fraud may proceed. Before this Court are two cases alleging that Baxter fraudulently reported prices of certain of its hemophilia drugs. Ven-A-Care's first-in-time complaints against Baxter describe the fraud in a manner that is interchangeable with the fraud it alleged against the dozen other pharma defendants sued in Ven-A-Care's case.

In contrast, Relators Linnette Sun and Greg Hamilton's later-filed complaint provides unique details about how key Baxter personnel carried out the Baxter-specific fraud. Only the Sun/Hamilton complaint makes claims and provides information relating to Advate, the only drug relevant to this first-to-file determination. Finally, the Sun/Hamilton complaint describes conduct by Baxter designed to thwart government-imposed price reporting guidelines that were not addressed in any Ven-A-Care complaint.

The question for this Court is whether Sun/Hamilton was first to provide the essential facts of the Advate fraud. No doubt the Ven-A-Care complaints were sufficient to point government investigators in the general direction of the fraud which Baxter eventually deployed with respect to Advate. Thus, if direction-pointing is all that were required, then this Court will imbue Ven-A-Care with first-to-file status on the Advate claims. If, however, the essential-facts test requires a False Claims Act complaint to provide the government more than a general industry-wide allegation – a more complete understanding of how this particular fraud was conducted by that particular defendant – then Ms. Sun and Mr. Hamilton are inescapably first-to-file.

In fact, the First Circuit's controlling analysis in *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 579 F.3d 13 (1st Cir. 2009), as well as the first-to-file ruling in

this MDL, hold that a complaint earns first-to-file status only if it reveals the required defendant-specific details necessary for a full understanding of the fraud. Such facts include information about the precise drug at issue. In contrast, allegations of a "broad scheme" that could be applied to any of a multitude of separate defendants do not suffice.

Only Sun/Hamilton – not Ven-A-Care – provided the type of insider information required by this Court and the Court of Appeals. Relator Linnette Sun, the former Director of Medical Outcomes Research and Economics at Baxter, was directly responsible for the pricing of Advate. She alleged in the Sun/Hamilton complaint the specific details of meetings she attended with other Baxter personnel that revealed Baxter's acknowledgement of its fraudulent pricing strategy for Advate. Relator Greg Hamilton was one of Baxter's main Advate customers and a direct target of Baxter's Advate marketing efforts. Thus, he had direct knowledge of the true market prices for Advate. In addition, Mr. Hamilton had direct communications with First DataBank ("FDB"), the conduit for Baxter's false price reporting. Mr. Hamilton alleged in the Sun/Hamilton complaint how Baxter misled FDB about Baxter's sales strategy to avoid revealing the true market prices for Advate.

In contrast to the Baxter-specific information alleged by Sun/Hamilton, Ven-A-Care's four amended complaints fail to detail Baxter's internal strategies and pricing schemes. The Ven-A-Care complaints make no mention of Baxter's employees, meetings, strategies, or communications. Instead, Ven-A-Care's allegations against Baxter consist of nothing more than generic allegations that Ven-A-Care incorporated verbatim into its claims against every one of more than a dozen pharmaceutical company defendants. The only allegations that apply exclusively to Baxter in the entire compendium of Ven-A-Care

complaints arise from price lists describing charges for Baxter products. There is not a single allegation to describe how Baxter, as distinct from the multitude of other defendants, carried out a pricing fraud – and continued to do so in its own unique way *after* government officials became aware of AWP fraud generally. Ven-A-Care has not alleged, nor identified any evidence to prove, that it ever had any direct contact with anyone from Baxter about its hemophilia products.[1] Moreover, Ven-A-Care fails to allege any contact with FDB about the manner in which Baxter carried out its pricing fraud. It is not even clear whether Ven-A-Care ever purchased any blood factor product (either Advate or Recombinate) directly from Baxter. Indeed, none of the Ven-A-Care complaints ever mention Advate in any way. Finally, Ven-A-Care's allegations with respect to Baxter's hemophilia drugs do not post-date 1999, other than a single line in a pricing spread exhibit. In contrast, Sun/Hamilton's complaint describes a fraud scheme unique to Baxter that was specifically designed to flout a new pricing regime mandated by the governments in 2000.

Given the contrast between the Sun/Hamilton complaint and the Ven-A-Care complaint, analyzed in the context of *Duxbury*'s "essential facts" test, there is only one plausible conclusion – Sun/Hamilton were first-to-file with regard to Baxter's Advate pricing fraud. Moreover, Baxter and Ven-A-Care passed over many obvious opportunities to raise the first-to-file issue on the Advate claim. Their late attempt to do so now, if not waived, only casts further doubt on the merits of their argument.

[1] This omission is in stark contrast to Ven-A-Care's claims against certain manufacturers, with which Ven-A-Care alleged it had direct conversations concerning the pricing and reimbursement of specific drugs, and with respect to which Ven-A-Care alleged conversations with payors. [*See, e.g.*, 1:10-cv-11186, ECF No. 6, at ¶¶ 152-153].

BACKGROUND FACTS

In 1995, Ven-A-Care began suing drug companies under the False Claims Act for overcharging Medicaid. In a sense, the rest is history: Ven-A-Care amassed a mighty armada of lawyers, filed a Byzantine maze of complaints, and amended those complaints multiple times to add and subtract various defendants or products. Eventually, Ven-A-Care became the most successful *qui tam* whistleblower to date. Its cases have reportedly recovered for the United States and state Medicaid programs more than $3 billion. *See* "A whistleblower and its 'pit bull,' " THE NATIONAL LAW JOURNAL & LEGAL TIMES, dated February 7, 2011 (copy available at www.taf.org/NLJ-Breen-Ven-a-Care%20(color).pdf), and attached hereto as Exhibit A). But Ven-A-Care, a self-described "very small infusion pharmacy," was an insider with respect to only a small fraction of the fraud it alleged. [1:10-cv-11186, ECF No. 6 at ¶ 196].

Ven-A-Care's first allegations of AWP fraud against Baxter were made in 1995. It named a multitude of Baxter drugs, including Recombinate, the factor VIII blood product for treatment of hemophiliacs. Ven-A-Care amended its complaint in 1997, 1999, and 2002. [1:10-cv-11186, ECF Nos. 3-7]. But the last time Ven-A-Care made any allegations against Baxter (other than updating drug pricing for two state Medicaid programs) was in its third amended complaint, filed in 1999 – nearly four years before the launch of Advate, and before the Department of Justice and the State Attorney Generals' Medical Fraud Conduct Unit mandated a new price reporting regime. In fact, although the 1999 Ven-A-Care complaint alleged pricing spreads for Baxter's drug Recombinate, those spread allegations *were eliminated* from the body of Baxter's final complaint, filed in 2002. [*Compare* 1:10-cv-11186, ECF No. 6 at pp. 202-209 *with* ECF No. 7 at pp. 92-97]. In its

complaints against Baxter, Ven-A-Care made generic fraud allegations that could apply to any drug of any of the defendants. Examples of such allegations include:

- "the common and wide spread use of the term 'Average Wholesale Price' (AWP) to describe drug prices in a manner whereby interested parties can make decisions that are affected by price." [1:10-cv-11186, ECF No. 6 at ¶ 48.]

- "drug manufacturers including the DEFENDANTS provide First Data Bank, Medical Economics and Medi-Span with the specific prices and costs of their drugs and instructions, if necessary, expressed in a manner that allows the price reporting companies to establish the necessary pricing information for publication that is utilized by Medicare, Medicaid and others in determining reimbursements for prescription drugs." *Id.* at ¶ 63.

- "[s]ome of the DEFENDANTS make representations of cost and price only in terms of 'List Price' " to which a markup is applied. *Id.* at 140. "The DEFENDANTS reported their representations of prices such as AWP, WAC, DP and list prices to First Data Bank." *Id.* at ¶ 179.

- "The vast majority of drug manufacturers, including the DEFENDANTS, are truthful when representing prices and costs of all or most drugs, except for the drugs at issue in this case." *Id.* at ¶ 70.

The allegations that named Baxter directly described the conduct no less generically. In the one section of its complaints supposedly focused exclusively on Baxter, Ven-A-Care simply included the pricing and reimbursement spread for certain Baxter drugs, and then copied virtually verbatim allegations from the sections devoted to various other pharma defendants. [*Compare, e.g.*, 1:10-cv-11186, ECF No. 6 at ¶ 196 *with* ¶¶ 198, 202]. Ven-A-Care's charts contained Baxter "AWP" and "DP" pricing along with "Relator's Cost" for Baxter drugs in the years 1993-1997. [1:10-cv-11186, ECF No. 6 at ¶ 196]. In other words, Ven-A-Care alleged that Baxter, among many other manufacturer-defendants, reported inflated prices for certain specified drugs, during certain specified years, and caused payors to reimburse a large spread. Totally missing from Ven-A-Care's complaint against Baxter is any specific information about the marketing, pricing or reporting strategies behind

Baxter's price lists, who from Baxter was involved, what was said to whom, and how Baxter knew that what it was doing was illegal. The only Baxter-specific information Ven-A-Care alleged was the names and widely-available prices of Baxter drugs.

Even with these generic allegations, Ven-A-Care was key to exposing a massive industry fraud. Thanks to Ven-A-Care, it was widely known by 2000 that the AWPs reported to FDB by pharmaceutical manufacturers like Baxter were unreliable. Indeed, a February 16, 2000 letter from the drug pricing team within the Office of the Attorney General Medicaid Fraud Control Unit (MFCU), which was sent sent to all Medicaid pharmacy directors, confirmed this fact:

> As you may be aware, a current national investigation by State and federal agencies has revealed a pattern of misrepresentations by some drug manufacturers of the average wholesale prices and wholesale acquisition costs of certain of their products. As a result of those misrepresentations, Medicaid and Medicare have substantially overpaid for these drugs and will continue to do so until corrective measures are implemented. To that end, First DataBank, Inc. ("FDB") has been cooperating with representatives of the State Medicaid Fraud Control Units in the development of procedures that will improve the accuracy and validity of the information provided to the States.
>
> * * *
>
> Stated briefly, under the impending change to current procedures, FDB will base the average wholesale prices it reports *on market prices*, rather than the prices identified by manufacturers. Additionally, FDB will no longer report a price for a product unless its manufacturer has certified the completeness and accuracy of the pricing information submitted.

See Exhibit B hereto (emphasis added).[2] Thus, after February 2000, if a pharmaceutical company wanted to report false prices to FDB to inflate government reimbursement for its

[2] A copy of the letter is publicly available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=19&ved=0CHAQFjAIOAo&url=http%3A%2F%2Fawp.doj.wi.gov%2Fawp%2FWestVirginia%2FTrialExhibits%2FWV_PLAINTIFFS_EXHIBIT_154.pdf&ei=COhiUd3SApDE0AH-sICgDw&usg=AFQjCNGMSht9dNBs7-iVJoAV3F32Gih6Dg&sig2=k1h7MG3hvT_4JD0TYLh_7w.

products, the company could no longer simply report a false AWP or WAC. It would have to prevent FDB from uncovering the drug company's actual market prices.[3]

Again, Ven-A-Care made no allegations against Baxter that related to Baxter's conduct under the new post-2000 pricing regime. Indeed, after 1999, Ven-A-Care made no new allegations at all about Baxter's hemophilia products (it only listed certain drugs in exhibits to its fourth amended complaint). In contrast, the Sun/Hamilton complaint expressly addresses Baxter's pricing fraud post-2000, and under the new MFCU pricing regime:

> Prior to May of 2000 FDB's misreporting of price information was suspected or known by state Medicaid agencies. However, in May of 2000 FDB entered into an agreement with the Department of Justice and various states to stop reporting AWPs published by the manufacturers and to instead report them on the basis of market prices. FDB subsequently based its reports on surveys of wholesalers. The states were thus lulled into a false sense of security about the integrity of subsequent AWP reporting.

[1:08-cv-11200, ECF No. 102 (Sun/Hamilton Second Amended Complaint) at ¶ 25].

The Sun/Hamilton complaint alleges a specific fraudulent scheme – unique to Baxter – whereby Baxter refused to report its "market-based" wholesale prices for its hemophilia products to FDB by claiming that it did not sell such products to "wholesalers." Instead Baxter made up and reported a "list price" to substitute for the true market price. That list price was still much higher than the price Baxter was actually charging to its primary customers. [*See* 1:08-cv-11200, ECF No. 102 at ¶¶ 36-48]. The Sun/Hamilton allegations include the specific dates and locations of meetings in which the fraud was planned and acknowledged, as well as the specific Baxter personnel involved. [*See* 1:08-cv-

[3] Baxter itself noted the difference in the post-2000 FDB reporting in a letter to the Center for Medicare and Medicaid Services, stating: "First DataBank's new definition of AWP – as apparently mandated by Department of Justice attorneys – is a radical departure from the actions previously demonstrated by First DataBank with respect to Baxter BioScience's therapies." (*See* 30(b)(6) Deposition of Baxter (Michael Bradley), 20:18-21:6; Dep. Exhibit 2, attached hereto as Exhibit C).

11200, ECF No. 102 at ¶¶ 39-48]. As this Court noted in finding Ms. Sun to be an original source of information regarding Baxter's pricing fraud:

> Relator Linnette Sun was hired by Baxter in 2002 as Director of Medical Outcomes Research and Economics. Her primary responsibility was pricing Advate. She attended a meeting at Baxter where employees crafted a plan to set an AWP for Advate but to disguise it in reports to FDB as the "list sales price." When she discovered what was happening after Baxter's "list sales price" was reported to FDB, she notified her superiors, who ordered her to drop the matter. Her employment with Baxter ceased on July 22, 2003. Baxter began reporting pricing information on Advate to publications on July 28, 2003.

[1:08-cv-11200, ECF No. 91 at p. 4]. Mr. Hamilton was also determined by the Court to be an original source based on his prior employment with Express Scripts and conversations with FDB representative Kay Morgan during the course of his employment. *Id.* at pp. 9-10. Ms. Sun is a prototypical corporate-insider whistleblower, and Mr. Hamilton brought the government actual, non-public knowledge about how Baxter was reporting its hemophilia products to FDB.

Ven-A-Care, by contrast, never alleged how Baxter's personnel carried out fraudulent conduct, never alleged or identified evidence that Ven-A-Care ever purchased or sold Advate, and never alleged or identified evidence that Ven-A-Care had direct contact with manufacturers surrounding the purchase of any anti-hemophilia drug. Ven-A-Care certainly never worked for, or had inside knowledge regarding, Baxter's marketing of Advate. Thus, Ven-A-Care was never in a position to, and never did, provide the "essential facts" of Baxter's Advate fraud. In fact, it has been reported that Ven-A-Care closed its pharmacy operations in the early 1990s. *See* Exhibit A.[4]

[4] Relators asked Ven-A-Care to disclose the date by which its pharmacy operations closed, but Ven-A-Care did not supply that information.

ARGUMENT

I. In Determining the "Essential Facts", the First Circuit Requires Specific Details, Not General Schemes.

All parties have acknowledged that the First Circuit's opinion in *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 579 F.3d 13 (1st Cir. 2009), controls here. *Duxbury* holds that a second-in-time relator who alleges the facts necessary to understand the details of a defendant's fraudulent scheme gains first-to-file status over a first-in-time relator who alleges the scheme only generically. In *Duxbury*, the original relator alleged that Ortho Biotech provided illegal kickbacks and engaged in off-label marketing to sell the drug Procrit. But according to the First Circuit, Duxbury's generalized allegations of off-label marketing were *not* sufficient to bar a later-filed complaint that contained important, specific information. The First Circuit's comparison between the original relator's off-label marketing allegations and the more specific allegations in a later-filed case are worth visiting in detail:

> The Relators contend that the Original Complaint, in particular, Paragraphs 40 through 42, allege all of the "essential facts" of the off-label promotion scheme. As the district court found, there are significant similarities between the "off-label" promotion allegations contained in those paragraphs and the allegations in the Blair Complaint. Both allege that OBP did not have FDA approval for "a dosing regimen of 40,000 units once per week." (*Compare* Original Compl. ¶¶ 40(c); 41; Blair Compl. ¶¶ 22-27). Both allege that OBP promoted this dosage in order to "increase . . . payments for each Medicare Beneficiary receiving Procrit for treatment." (*See* Original Compl. ¶¶ 40(c); 41; Blair Compl. ¶¶ 22-27). And both allege that the higher dosage resulted in the filing of false claims with the government. *See Duxbury*, 551 F.Supp.2d at 113 (noting these similarities).
>
> However, the Original Complaint and Blair Complaint differ in one crucial respect. As recognized by the district court, the Blair Complaint contained a number of allegations that discuss, in significant detail, OBP's promotion of the "off-label" use, and alleged such "promotion" efforts as

> (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit.
>
> *Id*. at 113 (citing Blair Compl. ¶¶ 27, 28-79). By contrast, Paragraphs 40 through 42 of the Original Complaint only allege one method by which OBP promoted the "off-label" use of Procrit, the use of "clinical trials," and, in particular, an unnamed "Phase IV Study" that "resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week-an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia." (Compl. ¶40(c)). As this allegation fails to encompass the other allegations contained in the Blair Complaint concerning OBP's "off-label" *promotion*, it fails to allege the "essential facts" of the "off-label" *promotion scheme* contained in the Blair Complaint. In fact, the Original Complaint nowhere refers to a "off-label" promotion scheme. Thus, we conclude that the Original Complaint cannot trump the Blair Complaint for purposes of the "first-to-file" rule.

Id. at 32-33. From the First Circuit's description of the original complaint in *Duxbury*, it is clear that the original complaint would have put the government on notice of an off-label marketing scheme to market the higher, unapproved dosage formula of Procrit. Nevertheless, this notice was not sufficient to qualify the first-in-time filer for "first-to-file" status. Rather, *Duxbury* held that the first-in-time complaint was missing critical details underlying the scheme at issue and was barred by the more specific, but later-filed, complaint.

Like the original complaint in *Duxbury*, the Ven-A-Care complaint only generally described Baxter's AWP fraud. Indeed, when it comes to the allegations against Baxter, Ven-A-Care alleged only the loose outlines of the fraud in a way that was applied identically to more than a dozen different companies. Moreover, as compared to *Duxbury*,

the Ven-A-Care complaints are not only missing "significant detail" surrounding Baxter's Advate-based pricing fraud; the Ven-A-Care complaints do not contain any allegations at all with respect to Baxter's pricing and marketing of Advate. The only paragraphs that even mentioned Baxter's conduct appear to be cut and pasted from allegations against other defendants. While the Ven-A-Care complaints do include a chart listing the pricing for Baxter drugs, these allegations tell the government nothing about how Baxter committed the fraud – the charts only disclose that a spread existed (for drugs other than Advate). Additionally, the Ven-A-Care complaints do not allege any information about Baxter's contacts with FDB or the manner in which Baxter reported prices under the post-2000 pricing regime.

By stark contrast, the Sun/Hamilton complaint significantly details how Baxter manipulated the price of Advate to procure for its customers an improperly inflated reimbursement from the state Medicaid programs. The scheme described by Sun/Hamilton differs from the generalized AWP pricing fraud that Ven-A-Care disclosed. [1:08-cv-11200, ECF No. 102 at ¶¶ 28-49]. The Sun/Hamilton Complaint describes specific Baxter meetings about pricing the two drugs at issue, and details a price-manipulation scheme distinct from the generalized AWP fraud described by Ven-A-Care. These differences are much greater than the differences between the earlier and later-filed complaints in *Duxbury*. Ven-A-Care not only failed to provide details about the pricing of the drugs at issue in the Sun/Hamilton case, it did not even mention the drug at issue. Many other courts have given first-to-file status to a second-in-time filing for similar reasons. *See, e.g., United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 58-59 (D. Mass. 2010), *rev'd on other grounds*, 647 F.3d 377 (1st Cir. 2011) (second complaint not barred where it detailed

specific manner in which kickbacks were provided to doctors across county because first complaint "made only passing 'information and belief' reference to false claims arising out of illegal kickbacks beyond Arkansas"); *United States ex rel. Diaz v. Kaplan Univ.*, 09-20756-CIV, 2011 WL 3627285 at *9 (S.D. Fla. Aug. 17, 2011) ("While these two cases have the same theory of liability, the False Certification theory, their claims under the False Claims Act do not rely on the same core facts or general conduct"). *United States ex rel. Harris v. Lockheed Martin Corp.*, 1:08-CV-3819-AT, 2012 WL 5866204 (N.D. Ga. Mar. 9, 2012) (denying motion to dismiss on first-to-file grounds where both cases involved fraudulent billing scheme by defendant at same aircraft production facility because second plaintiff alleged different details of scheme).

The first-to-file holdings set out in *Duxbury* and by the Court in this MDL make sense. It does not serve the government to reward generic allegations, untailored to a specific defendant, and thereby discourage corporate insiders from coming forward with specific information about the who, what, when, where, and why of a corporation's fraudulent conduct. In prose uniquely relevant here, the Ninth Circuit has cautioned against interpreting the first-to-file provision in a way that would permit "opportunistic plaintiffs with no inside information to displace actual insiders with knowledge of the fraud." *United States ex rel. Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 824 (9th Cir. 2005). *See also United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (*per curiam*) (stating that government lawyers, confronted with a *qui tam* complaint, are "not like pigs, hunting for truffles buried in [*qui tam* complaints]"). *United States ex rel. Goldberg v. Rush Univ. Med. Ctr.*, 680 F.3d 933, 935 (7th Cir. 2012) ("a very high level of generality is inappropriate,

because then disclosure of some frauds could end up blocking private challenges to many different kinds of fraud").

Generally speaking, it would be unfair to characterize Ven-A-Care as an "opportunistic plaintiff" with "no insider information." Ven-A-Care did a great service to the governments by disclosing rampant industry fraud and helping them recover billions of dollars. But in the context of this case, Ven-A-Care and Baxter now attempt to make very late use of the first-to-file doctrine, in hopes of jamming into their settlement very specific claims that Ven-A-Care did not bring. This strategy does not square with the law or the policy behind the False Claims Act.

II. First-To-File on Recombinate Does Not Equal First-To-File on Advate.

Sun/Hamilton believe the arguments in Section I, based solely on a comparison of the parties' respective complaints and application of the law, are dispositive. The arguments in Section I are not dependent on any disputed issues of fact that require live testimony.

Nevertheless, this Court has previously ruled that the first-to-file ruling may turn on the differences between the two Baxter drugs referenced in the Sun/Hamilton complaints: Recombinate and Advate. *See* Transcript of Proceedings dated Nov. 28, 2012 at pp. 27-28, attached hereto as Exhibit D ("I need to look at the facts of these two drugs, whether they were different enough or similar enough to put the government on notice"). Some of Ven-A-Care's complaints list the pricing spread of Recombinate, but none mention Advate. Notably, this Court has previously ruled (at the insistence of Ven-A-Care):

> Notice of fraud in one drug's pricing is not notice of fraud in another drug's pricing, as [defendant] well knows. This is because drugs are often marketed, reimbursed, sold, and priced in different ways. *See In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2007 WL 4287572, at *3

> (D.Mass. Dec. 6, 2007) ("The conclusory allegation of one 'broad scheme' is inadequate particularly in light of the evidence in this MDL demonstrating that each drug must be analyzed differently."). For this reason, this Court has required plaintiffs to plead the allegedly fraudulent average wholesale price of each drug with specificity under Rule 9(b). *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D.Mass.2003).

In re Pharm. Indus. Average Wholesale Price Litig., 2008 WL 2778808, *3 (D. Mass. July 15, 2008) ("*Abbott*"). To be clear, the Court qualified this ruling, noting that the specific drug named only in the second-in-time complaint (Erythromycin) had been marketed by a different division of Abbott than the drugs named in the original complaint. Presumably, the difference in divisions informed the Court's conclusion that failing to name the specific drug in the original complaint was fatal to the "first-to-file" argument.

In this case, there is no dispute that Recombinate and Advate were marketed by the same division of Baxter. But there are other differences between the drugs such that naming Recombinate in a complaint does not render a plaintiff first-to-file for Advate claims.

If differences between the drugs impact the first-to-file calculus, those differences favor Sun/Hamilton's first-to-file position on Advate, even though the two drugs were marketed by the same division. Sun/Hamilton do not believe there is much, if any, dispute about the similarities and differences between Recombinate and Advate. They are as follows:

Differences Between Recombinate and Advate:

1. Unlike Recombinate, Advate (referred to as "PFM" – plasma free method) is manufactured without exposure to human or animal proteins. (Transcript of 30(b)(6) Deposition of Baxter (Michael Bradley), attached hereto as Exhibit C, at 53:2-54:10, 57:21-60:13, 61:19-24, 151:17-152:6).

2. At the time Advate was launched, Advate, and its PFM, was considered by Baxter to be far and away the largest single opportunity for Baxter. (Exhibit C, at 61:8-14, 62:1-11, Dep. Exhibit 8 at p. 4).

3. At the time Advate was launched, it was expected to justify a price premium over Recombinate between 5 and 25%, and was, in fact, priced at a premium when it was launched. (Exhibit C, at 60:1-61:1, 64:7-65:6, 103:6-104:3, 62:1-24, Dep. Exhibit 9 at BAX STATE E 0447985-86).

4. Baxter hired new personnel for the launch of Advate. (Exhibit C, at 94:19-95:17).

5. Baxter built a new plant in Switzerland for the purpose of manufacturing Advate. (Exhibit C, at 101:19-102:5, Dep. Exhibit 13 at p. 11).

6. It is cheaper to manufacturer Advate than it is to manufacturer Recombinate. (Exhibit C, at 61:15-18).

Similarities Between Recombinate and Advate:

1. Recombinate is an anti-hemophilia biological product known as a recombinant and is used to treat blood factor VIII clotting disorders. Advate is also an anti-hemophilia biological product known as a recombinant and is used to treat blood factor VIII clotting disorders. (Exhibit C, at 11:22-12:14, 53:2-9, 101:19-102:5, Dep. Exhibit 13 pp. 4, 11).

2. Advate and Recombinate are manufactured by the same division at Baxter. They are also manufactured using some of the same processes and include the same active therapeutic ingredients. (Exhibit C at 110:8-11, 144:5-20).

3. Advate and Recombinate are marketed to the same market segments, health care providers and patients and are administered in the same manner to the same patients for treatment of the same condition. (Exhibit C at 110:21-111:5, 144:22-146:23).

4. Price representations about Advate and Recombinate were made to FDB by the same Baxter employees, and the decisions about what to report were made by the same Baxter management personnel. (Exhibit C at 109:11-110:7).

5. The price difference between the two drugs has declined over time. (Exhibit C at 105:6-12).

Given the differences in the respective marketing strategies for Recombinate and Advate, it is difficult to imagine how a complaint that just barely mentions Recombinate could describe the essential facts of an Advate fraud. Perhaps more important than the differences between the two drugs, however, was the Court's statement from the *Abbott* ruling that: "The conclusory allegation of one 'broad scheme' is inadequate particularly in light of the evidence in this MDL demonstrating that each drug must be analyzed differently." *Abbott*, 2008 WL 2778808, at *3 (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2007 WL 4287572, at *3 (D. Mass. Dec. 6, 2007)). The truth is that even with respect to Recombinate, Ven-A-Care's complaints allege "one broad scheme," and contain no allegations as to the way Recombinate was marketed or sold, or the corporate strategy behind how Recombinate's prices were formulated or reported to the databanks. Moreover, although Ven-A-Care filed its final complaint in 2002, that complaint made no new allegations to take into account the price fraud that Baxter implemented to thwart the post-2000 government pricing regime. In fact that 2002 complaint *eliminated* the

Recombinate chart from the body of the 1999 complaint, and relegated Recombinate to a single line referenced in an exhibit.

III. Baxter's and Ven-A-Care's Arguments Abuse the First-To-File Doctrine.

Baxter and Ven-A-Care attempt to use the first-to-file doctrine for the first time a full *four* years after the Sun/Hamilton litigation was unsealed and disclosed to them. [D. Colo. 1:05-cv-736, ECF No. 32]. In August 2010, Baxter filed an answer and affirmative defenses to the Sun/Hamilton complaint. [1:08-cv-11200, ECF No. 103]. In that document, Baxter raised the following affirmative defense:

> "**Third Affirmative Defense**: To the extent another False Claims Act *qui tam* case is under seal that was filed prior to that of the Relators, Relators' claims are barred under the "first to file" doctrine."

Id. at p. 12. Notably, the Ven-A-Care case against Baxter was *not* under seal at that time. If Baxter thought that the Ven-A-Care case covered the claims in Sun/Hamilton, it could have easily referenced it in its Third Affirmative Defense or another affirmative defense. It did not. Baxter later filed a "first-to-file" motion against Sun/Hamilton, arguing that Ven-A-Care was first-to-file, but again, only on the Recombinate claims. [1:08-cv-11200, ECF No. 65]. Neither Baxter nor Ven-A-Care sought to resolve, or even raise, any Advate first-to-file issues before negotiating or finalizing their settlement. If they truly thought the settlement was resolving Sun/Hamilton's claims, they were obligated to notify Sun/Hamilton of that fact so that the Court could conduct the very fairness hearing contemplated in this Court's August 7, 2012 Order, and address any first-to-file issues at that time. [*See* 1:08-cv-11200, ECF No. 193 at pp. 9-10 (citing 31 U.S.C. § 3730(c)(2)(B))]. This pattern of conduct by Baxter and Ven-A-Care only casts further doubt on the actual merits of their first-to-file arguments.

Presumably, Baxter and Ven-A-Care seek to characterize the first-to-file argument as "jurisdictional," and "unwaivable," thereby employing it at this late stage as the ultimate "gotcha." But the First Circuit has imposed limits on how late a jurisdictional argument can be raised. *See Honneus v. Donovan*, 691 F.2d 1 (1st Cir. 1982) (holding that it was too late to contest diversity jurisdiction in a 60(b)(6) motion). Baxter asked this Court for, and was awarded, summary judgment on Sun/Hamilton's False Claims Act claims without ever questioning this Court's jurisdiction to enter that judgment. The first-to-file issue is now raised in a Rule 60(b)(6) motion *in a separate case*, i.e. the *Ven-A-Care* case. Both Ven-A-Care and Baxter had opportunities to raise first-to-file issues on Sun/Hamilton claims either before the Baxter/Ven-A-Care settlement, or before Baxter implicitly acknowledged the Court's jurisdiction over the Advate claims when moving for summary judgment. They should not be permitted to contest the jurisdictional basis of a judgment entered in a separate case. It would be an abuse of the first-to-file doctrine to employ it under these circumstances.

IV. The Merits of Sun/Hamilton's Claims.

The merits of Sun/Hamilton's claims have no bearing on whether they were first-to-file them. Indeed, to the extent Ven-A-Care believes Sun/Hamilton's claims have no merit, that belief is only further evidence that Ven-A-Care did not undertake to file them: Why would Ven-A-Care have filed claims it believes are meritless?

Despite the irrelevance of the merits to the first-to-file determination, Baxter and Ven-A-Care spent much time during the recent first-to-file discovery period deposing Mr. Hamilton about the merits. Thus, to avoid the appearance that Sun/Hamilton are

strategically dodging the merits, they have attached an appendix of testimony and exhibits on the merits demonstrating the following points:

1. Baxter lied to FDB and the Department of Justice about whether it sold hemophilia products to wholesalers and invented what it admitted was a confusing definition of "wholesaler" so that Baxter could avoid disclosing its true pharmacy acquisition cost to FDB. (Exhibit C, at 25:14-26:21, 40:6-24, 44:11-16, 46:15-24, 47:10-15, 74:2-75:9, 20:3-17, Dep. Exhibit 2, 71:13-22, Dep. Exhibit 10).

2. Baxter never gave any thought to what actual price would be the closest proxy to a wholesale acquisition cost. (Exhibit C, at 72:23-73:21).

3. Instead, Baxter reported to FDB a price for Advate based not on the actual price it was charging to its biggest segment of customers, but instead on what the legal team thought it could charge under the definition Baxter invented. (Exhibit C, at 23:6-24:24, 68:8-69:2).

4. Baxter complained to FDB that it was reporting prices for Baxter recombinant drugs that were too low, without disclosing to FDB that the reported price was what Baxter actually charged its best customers. (Exhibit C, at 48:12-49:10, Dep. Exhibit 7).

5. Baxter instructed its employees not to talk to anyone about the actual prices. (Exhibit C, at 106:1-13, 148:1-149:20, Dep. Exhibit 14).

6. Baxter may have disclosed its actual prices directly to state Medicaid programs, but for a purpose other than to affect the programs' reimbursement price for Baxter's hemophilia products. (Exhibit C, at 78:10-80:24).

CONCLUSION

For the foregoing reasons, Relators Linnette Sun and Greg Hamilton request that this Court find that they were first-to-file on the Advate claims and order a hearing to determine: (1) whether the Ven-A-Care/Baxter settlement was fair, adequate and reasonable; and if it was, then (2) what portion of the settlement the Sun/Hamilton Relators should be awarded.

Dated: April 9, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that he caused a true and correct copy of **SUN/HAMILTON'S PRE-HEARING MEMORANDUM IN SUPPORT OF THEIR FIRST-TO-FILE POSITION** to be served via the Court's ECF/electronic mailing system on April 9, 2013, and/or via Federal Express or U.S. Mail, proper postage prepaid, on April 10, 2013, as indicated below, upon the following counsel of record:

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